

**R E M A R K S**

Applicants have received and carefully reviewed the Final Office Action of May 4, 2009 and the Advisory Action of September 14, 2009, in which claims 1-20 are pending and stand rejected. With this paper, claims 1, 8, 9, 10, 11, and 14-16 have been amended and claims 6, 7, 12, 13, 17, and 18 have been canceled without prejudice. Support for the amendments may be found in the specification, claims, and drawings as originally filed. No new matter has been added. Favorable consideration of the following remarks is respectfully requested.

***Claim Rejections under 25 U.S.C. § 103***

Claims 1-20 were rejected under 35 U.S.C. §103(a) as being unpatentable over Peters et al., U.S. Patent No. 5,549,552 (hereinafter “Peters”), in view of Mügge et al., U.S. Patent No. 5,478,620 (hereinafter “Mügge”). Applicants respectfully traverse the rejection.

Independent claim 1, as amended, recites:

1. A balloon catheter assembly comprising:
  - a first tubular member having a proximal portion and a distal portion with a lumen extending between the proximal portion and the distal portion;
  - a balloon having a proximal waist length, a distal waist length and an expandable region therebetween disposed about the distal portion; and
  - a tie layer disposed between the proximal waist length or distal waist length and the first tubular member, wherein the tie layer comprises a polyester polymer layer disposed on a polyamide polymer layer, the polyamide layer disposed between the polyester layer and the first tubular member.

Neither Peters nor Mügge, taken either alone or in combination, teach or suggest such a device. Peters is directed toward a balloon dilation catheter. The balloon is attached to the catheter shaft by either an adhesive or a tie layer. Peters discloses the distal inner tube is preferably made of high density polyethylene (HDPE), the outer tube 35 is preferably made of nylon (a polyamide) or HDPE, and the balloon is preferably made of PEBAX (polyether block amide). Peters discloses that if a tie layer is used, a modified HDPE may be used (see Peters, column 9, lines 16-17). Peters does not teach or suggest a tie layer having two layers or a tie layer including a polyester and a tie layer including a polyamide.

The Examiner states at page 3, “it would have been obvious to a person having ordinary skill in the art at the time the invention was made to have modified the tie layer of Peters with the

polyester and polyamide tie layer as taught by Mugge for connecting together the tubular members.” The Supreme Court in *KSR Int'l Co. v. Teleflex Inc.* quotes *In re Kahn*, 441 F. 3d 977, 988 (CA Fed. 2006), “[R]ejections on obviousness grounds cannot be sustained by mere conclusory statements; instead, there must be some articulated reasoning with some rational underpinning to support the legal conclusion of obviousness”. Emphasis added; see page 14 of the April 30, 2007 Decision. The Court further stated, “a patent composed of several elements is not proved obvious merely by demonstrating that each of its elements was, independently, known in the prior art. See page 14 of the April 30, 2007 Decision. The only motivation for combining the teachings of Peters and Mügge comes from Applicants’ own specification, which is improper. MPEP 2142 states, “However, impermissible hindsight must be avoided and the legal conclusion must be reached on the basis of the facts gleaned from the prior art.” Moreover, neither reference teach or suggest a tie layer having two layers as currently claimed.

As discussed above, Peters does not teach or suggest the preferred materials for the balloon dilation catheter are materials in which a polyamide polymer and a polyester polymer tie layer would adequately secure the balloon to the tubular member. Thus, even if one were to modify the device of Peters to include the tie layer of Mügge, as suggested in the Office Action, the device may not function as intended. Therefore, even if one were to combine Peters and Mügge, one would not arrive at the device as currently claimed.

Additionally, there is no motivation, suggestion, or other reason for one of ordinary skill in the art to modify the structure of Peters and/or Mügge to achieve the claimed structure. For at least these reasons, Applicants submit that claim 1, which recites “a tie layer disposed between the proximal waist length or distal waist length and the first tubular member, wherein the tie layer comprises a polyester polymer layer disposed on a polyamide polymer layer, the polyamide layer disposed between the polyester layer and the first tubular member,” is not obvious over the cited art. As independent claims 10 and 15 contain similar limitations, Applicants submit that these claims are allowable for at least these reasons as well. Similarly, claims 2-5, 8-9, 11, 14, 16, and 19-20, which depend from one of claims 1, 10 and 15, and add which significant limitations, are also believed to be in condition for allowance.

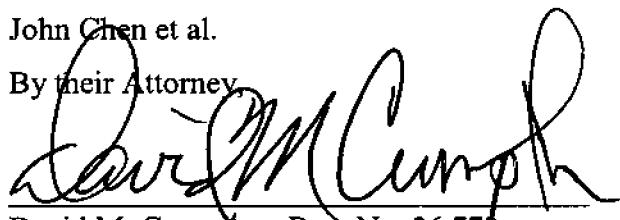
***Conclusion***

Reconsideration and further examination are respectfully requested. It is respectfully submitted that all pending claims are now in condition for allowance. Issuance of a Notice of Allowance in due course is requested. If a telephone conference might be of assistance, please contact the undersigned attorney at (612) 677-9050.

Respectfully submitted,

John Chen et al.

By their Attorney



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